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## IAP20 Rec'd FGT/FTO 08 FEB 2006 Ankle-joint endoprosthesis

- To replace the ankle joint, an endoprosthesis is known 5 comprising a component to be connected to the ankle bone, a component to be connected to the shin bone, and an intermediate part (DE-U-88 12 806, brochure "LINK S.T.A.R. Totale Sprunggelenk-prothese [H. Kofoed] from the company Waldemar Link (GmbH & Co.), Hamburg). The 10 ankle bone component and the intermediate part interact via slide surfaces which permit flexion and extension in the sagittal plane. The shin bone component and the intermediate part form interacting slide surfaces which permit a rotation about the vertical axis. They can be 15 of a plane design in order to permit compensating movements in the AP direction and LM direction. Stabilization is afforded by the natural ligament apparatus.
- In the known prosthesis, the top and bottom slide surfaces of the intermediate part are oriented parallel to one another in the frontal plane because the prosthetic replacement of the joint is not intended to result in a change in direction. However, it has been found that,

  25 after surgery, the collateral and medial ligaments of the joint often have different tensioning, which can cause problems. This may be due to irregularities of the anatomy or to the fact that the operating surgeon has chosen an unfavorable orientation of the resection surface provided on the shin bone for connection to the prosthesis.

The object of the invention is to avoid or alleviate an imbalance between, on the one hand, the anatomical or surgical circumstances and, on the other hand, the prosthesis.

The solution according to the invention lies in the

features of claim 1 and those of claim 5. Accordingly, the intermediate part and/or the shin bone component are of a wedge-shaped design. If the operating surgeon finds that the ligament tension is different if a normal prosthesis is used, he can compensate for this by using corrective components which have a wedge shape in the frontal plane. The thicker side of the wedge-shaped corrective plate is arranged on that side on which the ligament tension would be inadequate if normal components were used. If he finds that the tibial resection surface 10 is not perpendicular to the tibial direction or if he wishes, for other reasons, that the prosthesis planes do not extend perpendicular with respect to the axis of the tibia, he can also use corrective components whose wedge shape lies in the sagittal plane. If the operating sur-15 geon wishes that the lower slide surface of the upper component has a defined orientation with respect to the tibial direction or the direction of loading, he will generally use a shin bone component designed as corrective component. If, by contrast, the orientation of the 20 tibial resection surface is correct and the aim is to take account of the anatomy of the foot, he will prefer an intermediate part designed as corrective component.

The present patent does not relate to the wedge-shaped design of the intermediate part in the frontal plane since this is the subject matter of the earlier, not prior published patent application PCT/EP02/02573.

30 Determining that the upper component is wedge-shaped does not in practice cause any difficulties since both its top connection surface and also its bottom slide surface are plane or substantially plane. Comparison with the normal intermediate parts is decisive in determining any wedge shape of the intermediate part in the sagittal plane. Moreover, it is not only simple to determine the direction of the approximately plane top

slide surface of the intermediate part, but also the overall orientation of the bottom slide surface. An intermediate part is wedge-shaped, within the meaning of the present invention, in the sagittal plane when it becomes thicker anteriorly or posteriorly compared to the normal intermediate part.

A wedge shape in the sagittal plane can, in the context of the present invention, be combined with a wedge shape in the frontal plane. However, the wedge shape can occur in the sagittal or frontal plane also without a wedge shape in the frontal or sagittal plane.

The wedge angle is expediently between  $1^{\circ}$  and  $16^{\circ}$ , preferably between  $3^{\circ}$  and  $8^{\circ}$ .

To ensure that the orientation of the wedge shape of the intermediate part cannot be altered by rotation of the intermediate part about the vertical axis, its orientation is expediently forcibly fixed by way of the ankle bone or the shin bone, by means of the interacting slide surface pairs being designed accordingly in a manner which defines a direction (for example cylindrically). The joint between the ankle bone and the intermediate part is particularly suitable for this purpose.

To ensure that the operating surgeon can choose between different wedge angles, he must have access to several different corrective components for each prosthesis. To reduce the costs associated with this, it is expedient to design the corrective components as simply as possible. It may therefore be expedient for them to be made up of an unchanging standard part and of a wedge part. The standard part is provided in only one configuration. Only the wedge parts need to be provided in different variants. This applies in particular if the upper component is used as corrective component and the standard

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part forms the means necessary for securing to the shin bone.

- The invention is explained in greater detail below with reference to the drawing which depicts advantageous illustrative embodiments and in which:
  - Fig. 1 shows a sagittal section through a joint fitted with the prosthesis,

Fig. 2 shows the prosthesis in a perspective view and opened out,

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cesses 9 in the shin bone 1.

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- Fig. 3 shows a perspective view of the arrangement of
  the implanted upper and lower prosthesis components before the intermediate part is inserted,
  - Fig. 4 shows a frontal section through an upper corrective component,
  - Fig. 5 shows a sagittal section through an upper corrective component,
- Fig. 6 shows a sagittal section through a corrective intermediate part, and
  - Fig. 7 shows an upper corrective component which is designed in two parts.
- The prosthesis comprising the upper component 3, the lower component 4 and the intermediate part 5 is to be arranged between the shin bone 1 and the ankle bone 2. The upper component 3 has a plate-shaped part 6 whose bottom face 7 forms a plane slide surface. Projections 8 are used for securing it in corresponding resection re-

The lower component 4 forms a convexly curved slide surface 10 which can be designed cylindrically or conically. It carries a rib 11 which lies in the direction of the relative movement of the intermediate part during flexion and extension movement. The lower component additionally has lateral facets 12 for interaction with corresponding slide surfaces of the shin bone 1 and of the calf bone 13.

The intermediate part 5 has a plane top face 15 matching the slide surface 7, and a bottom slide surface 16 which is designed to complement the slide surface 10 of the lower component 4. It includes a groove 17 for receiving the rib 11. In this way, the intermediate part 5 is guided laterally in relation to the lower component 4. It is allowed only flexion and extension movements.

The upper and lower components 3 and 4 are expediently made of metal, and the intermediate part 5 of a plastic that promotes sliding, for example polyethylene. However, other materials with sufficient strength and slidability can also be used, for example ceramic.

On account of the complementary shape of the slide surfaces 10 and 16, and by the rib 11 interacting with the
groove 17, the intermediate part 5 is nonrotatable about
the vertical axis in relation to the ankle-joint component 4. Its orientation is thus fixed by that of the
lower component. While the embodiment shown completely
rules out rotation movements of this kind between the
lower component and the intermediate part about the vertical axis, configurations are also conceivable in which
these are permitted within predetermined limits or are
merely inhibited by the design of the slide surfaces or
are not ruled out.

The above explanation with reference to Figures 1 through 3 applies both to designs with normal components and also to designs with corrective components. Figures 4 through 6 show examples of corrective components. Fig. 4 shows a frontal view of an upper component 3 designed as corrective component. Near the edge 20 appearing on the left in the drawing, it is thicker than at the opposite edge. The component is designed symmetrically in relation to its frontal midplane, such that the thickened side 20 may lie on the lateral side or medial side of the joint, depending on the choice made by the operating surgeon.

Fig. 5 shows a sagittal section through the upper component 3. It is thickened in a wedge shape at the end 21 appearing on the left in the drawing. The top face of this component is symmetrical in relation to the frontal plane. Therefore, the thickened end can be arranged anteriorly or posteriorly in the joint, depending on the choice made by the operating surgeon. The wedge angle 22 between the top securing surface 23 and the lower slide surface 7 is of the order of magnitude of 5° in both examples.

Fig. 6 shows a sagittal section through a corrective intermediate part 5. Its bottom face 16 designed as slide surface has an overall orientation extending approximately parallel to the auxiliary line 24 which has been drawn in order to illustrate the wedge angle 19 near the top slide surface 15. In this case it is assumed that the line 24 in the normal intermediate parts extends parallel to the overall direction of the bottom face 16. The critical factor in determining a wedge shape of the intermediate part is always the comparison with the normal components of the prosthetic system.

It is not necessary for a correction to be restricted in each case to just one component. Instead, corrective

components can be used both for the upper component and also for the intermediate part. This possibility is shown in Fig. 1.

As soon as the operating surgeon has implanted the lower 5 component 4, he can use suitable instruments to determine whether, when the collateral ligaments are tensioned, the resection surface 25 of the shin bone has a normal extension relative to the lower component 4 or whether a correction is necessary. In the latter case, he decides whether a corrective component needs to be 10 selected for the upper component or the intermediate part or for both and he decides how pronounced the respective wedge shape needs to be and in what direction it should lie. A corresponding measurement is also still possible when the upper component 3 has been fitted. 15 Thereafter, it is possible to decide whether a corrective component is to be used as intermediate part.

Fig. 7 illustrates the composition of the upper compo20 nent 3 made up of a standard part 25 and a wedge part
26. Since the standard part 25 forms the securing members 8, the wedge part 26, of which several examples
with varying wedge angles are made available, can be
made correspondingly simpler. The two parts can be con25 nected to one another in any desired and known manner.
For example, they can be screwed together. They can also
be provided with complementary projections and recesses
engaging in one another, making it possible to join the
two parts together without any great effort.